

REMARKS/ARGUMENTS

Careful consideration has been given to the Examiner's Office Action and the cited references. It is respectfully requested that the Examiner reconsider and withdraw the prior art rejection in view of the following comments.

The pending claims include only one independent claim, i.e., claim 17. The Examiner has rejected independent claim 17 under 35 U.S.C. 103(a) as being obvious in view of: (1) the combined teachings of Pai et al. (US 6,156,267), Childers (WO 97/47331) and Kazi et al. (US 5,578,280) and (2) the combined teachings of Pai et al., Childers, Kazi et al. and Centanni et al. (US 7,087,805).

The applicant has carefully reviewed the cited references and the Examiner's arguments in support of the above-mentioned **Obviousness Rejections (1) and (2)**. Specific arguments made by the Examiner in support of a finding of obviousness with respect to independent claim 17 will now be addressed in detail.

Obviousness Rejection (1)

Referring to the limitation recited in claim 17 that requires the step of "simultaneously introducing said vaporized hydrogen peroxide and said ozone gas into the region," the Examiner states that "Pai teaches combining vaporized hydrogen peroxide and ozone *without teaching the simultaneous introducing of both sterilants*." (Emphasis added.) The Examiner then presents arguments as to why this limitation of claim 17 would have been obvious to one of ordinary skill in the art based upon a reading of the Pai et al. reference *and the applicant's own disclosure*.

First, the Examiner notes that "one of ordinary skill in the art would recognize that only three ways of introducing the sterilants are possible, where either one sterilant is introduced first before the other sterilant, or one sterilant is introduced after the other sterilant has already been introduced, or the simultaneous introduction of both sterilants." Next, the Examiner focuses his argument on the *applicant's own disclosure*. In particular, the Examiner states that "Applicant teaches combining ozone and vaporized hydrogen peroxide (page 3, paragraphs 0013, 0015, and 0021), or the simultaneous introduction of both sterilants (paragraph 0001), or decontaminating with ozone alone (paragraph 0048), or decontaminating with vaporous

hydrogen peroxide alone (paragraph 0047).” It is further noted with respect to the *applicant's own disclosure* that “[t]he specification does not teach advantageous or unexpected results for the simultaneous introduction of both sterilants.”

In view of the foregoing, the Examiner concludes that “one of ordinary skill in the art would realize upon reading the Pai reference *and the specification* that the order of introducing the sterilants is an obvious matter that is well within the purview of the artisan as evidenced by the Pai reference and *Applicant's disclosure*. Only the predicted results are attained.” (Emphasis added.)

It appears from the foregoing comments that the Examiner is relying at least in part upon the *applicant's own disclosure* of the present invention for establishing obviousness. It is respectfully submitted that the applicant's own disclosure cannot be relied upon for establishing obviousness without the use of impermissible hindsight.

The Examiner has acknowledged that the Pai et al. reference does not teach the *simultaneous* introduction of vaporized hydrogen peroxide and ozone gas into a region, but then finds that it would have been obvious to do so using the system taught by Pai et al. based upon the *applicant's own teachings*.

Furthermore, it is unclear what law the Examiner relies upon for finding obviousness based upon the applicant's disclosure that describes alternative embodiments of the present invention, namely, the simultaneous introduction of ozone and vaporized hydrogen peroxide, or the separate introduction of ozone and vaporized hydrogen peroxide into the region. The applicant has chosen to claim only one of the disclosed embodiments, and the applicant's representative is unaware of any caselaw that finds an invention obvious because the applicant has claimed only one of several disclosed alternative embodiments of the invention.

Moreover, with respect to the Examiner's comment that the applicant's specification does not teach advantages or unexpected results for the simultaneous introduction of both sterilants, the Examiner's attention is directed to the comments provided by the applicant on page 6 of the Response filed August 11, 2008. As noted therein, the simultaneous introduction of both vaporized hydrogen peroxide and ozone gas into a region provides synergistic effects, namely, the formation of a hydroxyl radical that acts as an efficient sterilant.

In **Obviousness Rejection (1)**, the Examiner further acknowledges in the current Office Action (see pages 3-4) that Pai et al. fails to teach several additional features of the claimed invention, namely: 1) circulating a carrier gas through a closed-loop system; 2) generating vaporized hydrogen peroxide using a vaporizer disposed in a conduit downstream of the ozone generator; 3) removing moisture by use of a dryer; 4) removing moisture from all of the carrier gas; 5) generating ozone gas using oxygen molecules of the carrier gas; and 6) destroying vaporized hydrogen peroxide.

With respect to the claimed step of circulating a carrier gas through a closed-loop system, the Examiner makes the following comments with respect to Childers:

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method in Pai with the sterilant/carrier gas recirculating closed loop system of Childers, because superior kill potentials and more efficient sterilization is obtained by partially and selectively drying the carrier gas in response to the sterilization parameters as explained by Childers (page 5, lines 25-37).

It is respectfully submitted that the foregoing argument does not support a finding of obviousness with respect to the recited claim limitation. In this regard, the Examiner argues that because superior kill potentials and more efficient sterilization are obtained by partially and selectively drying the carrier gas, it would have been obvious to "provide the method in Pai et al. with the sterilant/carrier gas recirculating closed-loop system of Childers." However, it is unclear how a teaching for *drying* carrier gas provides a rationale to one of ordinary skill in the art to use the method disclosed in Pai et al. in connection with a *sterilant/carrier gas recirculating closed-loop system*. In other words, it is unclear how drying carrier gas renders a recirculating closed-loop system an obvious modification of the method disclosed in Pai et al.

Furthermore, it is respectfully submitted that Kazi et al. also fails to teach or suggest a closed-loop system wherein both ozone gas and vaporized hydrogen peroxide are generated and simultaneously introduced into a region to effect inactivation of biocontamination.

Obviousness Rejection (2)

The Examiner repeats several of the arguments discussed above in connection with Obviousness Rejection (1). For instance, the Examiner makes the same obviousness

arguments with respect to the step of circulating a carrier gas through a closed-loop system. As discussed in detail above it is unclear how a teaching for drying carrier gas provides a rationale to one of ordinary skill in the art to use the method disclosed in Pai et al. with a sterilant/carrier gas recirculating closed-loop system.

Moreover, the 35 U.S.C. 103(a) rejection of **Obvious Rejection (2)** relies upon Centanni et al. (US 7,087,805) which qualifies as prior art only under 35 U.S.C. 102(e). However, it is submitted that Centanni et al. (US 7,087,805) is *disqualified* as prior art under 35 U.S.C. 103(c), since the subject matter of Centanni et al. and the claimed invention were *commonly owned* at the time the claimed invention was made. See MPEP Section 706.02(l)(2) and 706.02(l)(1).

STATEMENT OF COMMON OWNERSHIP

U.S. Patent Application No. 10/734,059 to Centanni and U.S. Patent No. 7,087,805 to Centanni et al. were, at the time the invention of U.S. Application No. 10/734,059 was made, commonly owned by STERIS Inc.

In view of the disqualification of Centanni et al. (US 7,087,805), it is respectfully submitted that **Obviousness Rejection (2)** should be withdrawn.

Law on Obviousness

As the Examiner is aware, the U.S. Supreme Court decision in *KSR International Co. v. Teleflex Inc.* (2007), 82 U.S.P.Q.2d 1385 has formed the basis of the USPTO Examination Guidelines published October 10, 2007 (Federal Register/Vol. 72, No. 195). As the United States Supreme Court has made clear in *KSR*, slip op. at 14:

Often, it will be necessary ... to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an *apparent reason* to

combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis *should be made explicit*. (Emphasis added.)

The Supreme Court in *KSR* noted that “it can be important to identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does.” (82 U.S.P.Q. 2d at 1389) In *PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, (Fed. Cir. 2007) 491 F.3d at 1364, 83 U.S.P.Q.2d (BNA) at 1304-05 (quoting *O’Farrell*, 853 F.2d at 903, 7 U.S.P.Q.2d (BNA) at 1681), the majority noted:

On the other hand, the court explained, an invention would not be invalid for obviousness if the inventor would have been motivated “to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful.” *Likewise, an invention would not be deemed obvious if all that was suggested “was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.”* (Emphasis added.)

In view of the foregoing comments, it is respectfully submitted the invention as defined by independent claim 17 is neither anticipated nor obvious in view of the cited references. Moreover, it is submitted that claims 20-28 (which depend from claim 17) are likewise patentability distinguishable from the cited references.

Conclusions


In view of the foregoing comments, it is respectfully submitted that the present application is now in proper condition for allowance. If the Examiner believes there are any further matters that need to be discussed in order to expedite the prosecution of the present application, the Examiner is invited to contact the undersigned.

Please note that an Information Disclosure Statement (IDS) accompanies this Response. The Examiner is respectfully requested to consider the references cited therein.

If there are any fees necessitated by the foregoing communication, please charge such fees to our Deposit Account No. 50-0537, referencing our Docket No. ST8613US.

Respectfully submitted,

Date: **December 11, 2008**



Michael A. Jaffe
Registration No. 36,326

Kusner & Jaffe
Highland Place – Suite 310
6151 Wilson Mills Road
Highland Heights, Ohio 44143
(440) 684-1090 (phone)
(440) 684-1095 (fax)

MAJ/lc